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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,998	08/18/2003	John D. Hatlestad	GUID.058PA	2963

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EXAMINER	
MUSSELMAN, TIMOTHY A	

ART UNIT	PAPER NUMBER
3714	

MAIL DATE	DELIVERY MODE
02/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,998	HATLESTAD ET AL.	
	Examiner	Art Unit	
	TIMOTHY MUSSELMAN	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14 and 35-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14 and 35-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

In response to the correspondence dated 12/26/2007, claims 1-12, 14, and 35-46 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 1-12, 14, and 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 5,520,176) in view of Walsh et al. (US 6,200,265) and 'Aircraft Noise and Sleep Disturbance: Final Report', prepared by the Civil Aviation Authority London on behalf of the Department of Trade, August 1980.

Regarding claims 1 and 35-36, Cohen discloses a system and methods for sleep quality data collection and analysis utilizing various measured physiological parameters. See col. 2: 33-59. Cohen fails to teach of utilizing non-physiological parameters in the research process. However, a *research* study conducted by the Civil Aviation Authority London published in 1980 pertains explicitly to this very subject. See page two, in the report summary, wherein it is described how aircraft noise was *measured* in various London neighborhoods on aircraft approach paths to the two main London airports in order to better understand how the noise interfered with the *sleep*

processes of residents. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate background noise measurements (i.e. non-physiological parameter measurements) in the manner of the 1980 CAA *sleep quality research* project, into the *sleep research* System of Cohen, in order to expand the usefulness of the research system of Cohen to include cause and effect data pertaining to sleep problems. Cohen additionally fails to teach wherein the collection and storing of sleep quality data occurs via an implantable device (**claims 1 and 36**). However, Walsh discloses utilizing implantable devices to detect and store measured physiological data. See col. 2: 30-48. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a device as disclosed by Walsh, in the system of Cohen, because such a combination would not produce any unexpected results, but would merely be a combination of elements known in the art at the time of the invention.

Regarding Claims 2-6 and 8-12, Cohen further discloses the detection and determination of metrics pertaining to; cardio-vascular conditions (**Claim 2**), see col. 6: 12-20; respiratory and disordered breathing conditions (**claims 3, 11, 39, and 43),** see col. 4: 3-10 and col. 4: 41-45; muscle system and movement disorder conditions (**claims 4, 12, 40, and 44**), see col. 8: 38-45; blood chemistry conditions (**claim 5**), see col. 5: 33-35; nervous system conditions (**claim 6**), See col. 8: 38-54; contextual conditions (**claim 8**), see the provided citations for claims 2-6; and data pertaining to sleep stages and sleep disruptions (**claims 9-10 and 37-38**), See col. 7: 20-25.

Regarding claim 7, the detection of environmental conditions (e.g. background noise) for sleep research is an obvious variation of Cohen in view of the CAA report as described above with regard to claim 1.

Regarding claims 14 and 46, Cohen further discloses transmitting the collected sleep quality data to a different device. See fig 1, labels 12-17.

Regarding claims 41-42, Cohen further discloses determining and trending the measured sleep quality metrics over time. See col. 3: 17-37.

Response to Arguments

Applicant's arguments dated 12/26/2007 have been fully considered and are not persuasive.

Applicant argues that the combination of Cohen, the CAA report, and Walsh, fail to disclose collecting and storing sleep quality information via an implantable device. It is true that Cohen and the CAA report do not disclose an implantable device. However, Cohen discloses detecting physiological sleep quality parameters for research. See col. 2: 33-59. The CAA report discloses detecting non-physiological sleep quality parameters for research (aircraft noise). See page 2 in the report summary. Walsh discloses that detecting *physiological* parameters with implantable devices is old and well known. See col. 2: 30-48.

The combination is obvious, because Cohen discloses detecting sleep quality parameters and the simple addition of other sleep quality parameters already known in the art and taught by at least the CAA report would not involve an inventive step, but would merely be combining elements already old and well known in the art, i.e. the expansion of the Cohen system to include additional known sleep parameters, an expansion that Cohen is well suited for since it is a general sleep research system (col. 2: 33-59). The same is true for the implantable device issue that applicant argues. Applicant is not claiming a novel implantable device, but merely that data is collected in part by an implantable device. As taught by Walsh, implantable devices are old and well known. The mere use of an implantable device to detect *physiological* parameters, as well known in the art, would merely be the fulfillment of the *exact established use* of implantable devices. This does not involve an inventive step, but is rather just using known devices for their intended purposes.

The reason why applicants arguments that the implanted devices are not used to collect *non-physiological data* are not persuasive is because this is not claimed. Rather, applicant has claimed wherein collecting the *data* is performed *at least in part* by an implantable device.

Collecting the *physiological* portion of the data with an implantable device as taught by Walsh would fulfill this limitation, as the physiological data is *at least a part* of the data. There is no claim language limiting the *non-physiological* portion of the data to the implantable device.

Examiner does not understand the relevance of applicant's argument that data is not transmitted to the implantable device of Walsh. This issue is not claimed. It is noted that claim 35 claims wherein *one of* collecting the data *or* evaluating the data is performed by the implantable device. Walsh discloses at least collecting and storing the data in col. 2: 30-48. Examiner can find no claim language requiring transmitting data collected external to the patient to the implantable device. Further, it is confusing how this correlates with applicant's previous argument that the references did not show each and every element on the basis that Cohen and the CAA report do not disclose detecting non-physiological data with an implantable device. The arguments seem at least slightly at odds, because the first argument claims that the combination is invalid because data in not collected internally, and the second argument claims the combination is invalid because data is not collected externally. However, it is examiner's position that the mere collection of data both internally *and* externally to a patient are old and well known in the art, as described above.

Applicant's argument regarding a lack of motivation for the combination of the above references is not valid. The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at ___, 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson ’s-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152,

87 USPQ 303, 306 (1950).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy Musselman whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./

Acting Examiner of Art Unit 3714

TM

/Ronald Laneau/

Supervisory Patent Examiner, Art Unit 3714

02/23/08